Court, U.S.
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No. 95-788

In the Supreme Court of the United States

OCTOBER TERM, 1995

MARY DOE, ET AL., PETITIONERS

v.

DONNA SHALALA, SECRETARY OF HEALTH AND HUMAN SERVICES, ET AL.

ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FOURTH CIRCUIT

BRIEF FOR THE FEDERAL RESPONDENTS IN OPPOSITION

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QUESTION PRESENTED

Whether a suit under the Federal Advisory Committee Act, 5 U.S.C. App., seeking to enjoin the release and consideration of a government report is rendered moot by the release and consideration of that report.

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OPINIONS BELOW

The opinion of the court of appeals (Pet. App. 3a-8a) is unpublished, but the judgment is noted at 57 F.3d 1066 (Table). The opinion and judgment of the district court (Pet. App. 9a-30a) are reported at 862 F. Supp. 1421.

JURISDICTION

The judgment of the court of appeals was entered on June 16, 1995. A petition for rehearing was denied on August 18, 1995. Pet. App. 1a-2a. The petition for a writ of certiorari was filed on November 16, 1995. The

jurisdiction of this Court is invoked under 28 U.S.C. 1254(1).

STATEMENT

1. This case was brought under the Federal Advisory Committee Act (FACA), Pub. L. No. 92-463, 86 Stat. 770, 5 U.S.C. App. 1 *et seq.*, to block issuance of a report by the Human Embryo Research Panel of the National Institutes of Health (NIH). The FACA regulates the use of the "numerous committees, boards, commissions, councils, and similar groups" that advise "officers and agencies in the executive branch of the Federal Government." FACA § 2(a); see *Public Citizen* v. *United States Dep't of Justice*, 491 U.S. 440, 445-446 (1989). Among other things, the statute generally requires federal advisory committees to file a charter, FACA § 9(c), to provide advance notice of their meetings and open those meetings to the public, § 10(a), and to make publicly available their minutes, records and reports. § 10(b). The statute also requires that the membership of FACA committees created by the President or other federal officials "be fairly balanced in terms of the points of view represented and the functions to be performed by the advisory committee." § 5(b)(2) and (c).

The Human Embryo Research Panel (the Panel) was established in January 1994 to assist a separate committee, the Advisory Committee to the Director of NIH in addressing "various areas of research involving the ex utero preimplantation human embryo and to provide advice as to those areas that (1) are acceptable for Federal funding, (2) warrant additional review, and (3) are unacceptable for Federal support." Nat'l Insts. of Health, *Report of the Human Embryo*

Research Panel at ix (Sept. 1994) (*Report*).[1] In addition, the Panel was asked to recommend guidelines for the review and conduct of those areas of research considered acceptable for federal funding. *Ibid.* The Panel held five public meetings between February and June 1994. Notice of each of those meetings was published in the Federal Register, and participation by interested individuals and organizations was encouraged. See 59 Fed. Reg. 2414 (Jan. 14, 1994); *id.* at 8996 (Feb. 24, 1994); *id.* at 14,173 (Mar. 25, 1994); *id.* at 19,200 (Apr. 22, 1994); *id.* at 28,874 (June 3, 1994).

2. Petitioners are (1) an unnamed human embryo identified as "Mary Doe," (2) the International Fund for Genetic Research (the Michael Fund), which researches Down's Syndrome and similar chromosomal disorders, and (3) Michael Policastro, a 24-year-old man afflicted with Down's syndrome. Before the Panel issued its report, petitioners brought suit against the Secretary of Health and Human Services (the Secretary), NIH and its director, and the Panel and its members. Petitioners sought to enjoin the Panel's activities on the ground that the membership of the Panel was not "fairly balanced" within the meaning of the FACA. See FACA § 5(b)(2).

After hearing argument, the district court entered summary judgment for the government, finding that "considerations of standing and justiciability" were "dispositive of the case." Pet. App. 15a-16a. The court held that the claims of petitioner "Mary Doe" should be dismissed because "embryos are not persons with legally protectable interests within the

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[1] Petitioners have lodged a copy of the Panel's report with the Court.

meaning of Fed[eral] R[ule of] Civ[il] P[rocedure] 17(c) such that appointments of *guardians ad litem* are warranted or required." Pet. App. 17a. The court determined that the other two petitioners lacked standing to bring their claims, because they had not shown they would be injured by the Panel's activities. The court explained that, "[e]ven if, following a report of the Panel, NIH were to elect to fund fetal research projects (and it is by no means certain to what extent it will), there is no basis for concluding that decision would diminish funding for research projects involving Down's Syndrome or other genetic disorders" or "for suggesting that Plaintiff Michael Policastro's life might [thereby] be at risk." Pet. App. 22a. In addition, the court noted (Pet. App. 23a) that the governing statute allows otherwise approved embryo research to be funded unless either an ethics advisory board advises the Secretary that it should not go forward or the Secretary decides to overrule a board recommendation in favor of such funding. See 42 U.S.C. 289a-1(b); Pet. App. 13a. Thus, the court observed, "preventing the Panel from issuing a report could well have no effect whatsoever on the ultimate decision of the Secretary to fund such research." Pet. App. 23a.

The court also held that petitioners' claim that the Panel was not "fairly balanced" under the FACA was nonjusticiable. Pet. App. 24a-28a. The court noted that the Panel's mission is "extremely broad to consider all possible areas of research involving the extracorporeal human embryo and to provide advice as to each." *Id.* at 28a. It found " 'no principled basis' upon which it could determine which among myriad points of view deserve representation on the Panel,"

and concluded that "[m]eaningful standards" to do so "are altogether lacking." *Ibid.*[2]

On September 27, 1994, the day after the district court issued its opinion, the Panel issued its report. Among other things, the report concluded that "sufficient arguments exist to support the permissibility of certain areas of research involving the preimplantation human embryo within a framework of stringent guidelines." *Report*, at x. The Panel's report was formally presented to and discussed by the Advisory Committee to the Director of NIH at a public hearing on December 1-2, 1994. At that meeting, the Advisory Committee voted to accept the Panel's report. Pet. App. 93a-101a. However, in December 1994, President Clinton announced that he had directed that NIH not allocate federal resources to support "the creation of human embryos for research purposes." Pet. App. 102a. The Panel's other recommendations remain under consideration, and to date no decision has been made by the Director of NIH or the Secretary with regard to the federal funding of other forms of human embryo research.[3]

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[2] After the district court denied their request for a stay and injunction pending appeal, petitioners unsuccessfully sought a stay and injunction pending appeal from the court of appeals. Petitioners thereupon sought a stay pending appeal from this Court, which was denied by the Chief Justice. *Doe* v. *Shalala*, Application No. A-456 (Dec. 23, 1994).

[3] The House of Representatives has passed an appropriations bill (H.R. 2127, 104th Cong., 1st Sess. (1995)) for the Department of Health and Human Services, under Section 511 of which the Department would be prohibited from using appropriated funds for the creation of human embryos for research purposes, or for research in which human embryos are "destroyed, discarded, or knowingly subjected to risk of

In an unpublished per curiam opinion, the court of appeals held that the case had become moot. Pet. App. 8a. The court explained that "[b]ecause the Panel has concluded its meetings, has issued its report and recommendations, and is apparently no longer in existence, an order dissolving the Panel, or enjoining it from holding further meetings or issuing its recommendations, would be pointless." Pet. App. 7a. In addition, the court found that it would be "a futile gesture" for it to "issue an injunction preventing NIH from considering the Panel's recommendations," since "the Panel's report and recommendations have already been considered by NIH and indeed by the President." *Id.* at 7a-8a. The court thus concluded that it would be unable to grant the relief requested by petitioners even if it were to rule in their favor. *Id.* at 8a. The court of appeals therefore vacated the district court's judgment and remanded the case with instructions that the action be dismissed as moot.

ARGUMENT

Petitioners renew their claims that "Mary Doe" has standing to challenge the composition of the Panel (Pet. 11-16) and that the composition of the Panel presents a justiciable issue (Pet. 16-20). The court of appeals, however, did not address those issues, but instead held that petitioners' FACA claims had been rendered moot by the release and consideration of the Panel's report. That fact-bound determination does not conflict with the decision of any other court and is neither of general nor of

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injury or death greater than that allowed for research on fetuses in utero." *Ibid.* The Senate has not acted on that bill.

continuing significance. Review by this Court is therefore unwarranted.

1. As the court of appeals explained, petitioners' request for an injunction against release and consideration of the Panel's report is moot. The Panel presented the report to the Advisory Committee to the Director of NIH in September 1994, and the report and its recommendations have been under consideration by NIH since that time. Moreover, the President has already taken the report into consideration, as reflected in his directive that certain human embryo research not be funded. It is obviously beyond the power of a court to enjoin the release and consideration of a report that has already been released and considered. See *Public Citizen* v. *Department of Health & Human Servs.*, 795 F. Supp. 1212, 1222 (D.D.C. 1992) (because the "seeds" of the committee's ideas have already been planted, "[t]o repeal the recommendation now would be inconsequential").

Petitioners acknowledge (Pet. 21) that the Panel's report "has already been disclosed and considered to some extent by NIH and the President." They nonetheless contend (*ibid.*) that "appropriate injunctive relief" could "preclude Government decisionmakers from citing or using [the Report] in the future to justify the funding of human embryo research." However, preventing federal officials from using or citing a publicly available report would not prevent federal funding of human embryo research in this case, since the government is free to fund such research whether or not it may explicitly refer to the Report and its recommendations. Petitioners concede as much. Pet. 15 (citing Pet. App. 23a); see 42 U.S.C. 289a-1(b) (agency may fund research so long as

an ethics advisory board does not recommend against research). Petitioners nevertheless speculate that "[a]s a practical matter, the current Administration" would not fund human embryo research "without being able to point to this Panel's Report[] to justify its decision." Pet. 22. But the applicable statute does not prohibit the government from funding such research without referring to the Panel report, and petitioners' speculation about what might or might not be "practical" does not save their case from mootness.

Nor are petitioners' claims "capable of repetition, yet evading review." See Pet. 22 n.12 (citing *Southern Pac. Terminal Co.* v. *ICC*, 219 U.S. 498 (1911)). First, there is no reason to assume that petitioners would raise any objections under FACA to any future group that might be constituted to address similar issues. Second, there is no basis to think that any such group, if constituted, would take an appreciably shorter time than the nine months it took the Panel in this case to prepare and present its report and recommendations. That period of time is ordinarily sufficient to provide litigants with an opportunity to obtain judicial review, particularly since the courts have tools at their disposal to expedite their proceedings. See, *e.g.*, *Washington Legal Foundation* v. *Unired States Sentencing Comm'n*, 17 F.3d 1446, 1448 (D.C. Cir. 1994) (expediting appeal to avoid potential mootness).[4]

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[4] It would in any event distort FACA's disclosure goals to invoke the Act to enjoin an agency from acting in reliance on the conclusions and recommendations contained in an otherwise publicly available report. See *National Nutritional Foods Ass'n* v. *Califano*, 603 F.2d 327, 336 (2d Cir. 1979) (refusing to invalidate agency rule adopted in reliance on report prepared

2. Petitioners' challenge to the composition of the Panel also does not warrant this Court's review because, as the district court found, petitioners do not have standing and their claim is not justiciable. See Pet. App. 16a-24a, 24a-28a.

a. In the ordinary FACA case, plaintiffs assert that they have been denied *access* to an advisory committee's proceedings in violation of the FACA's public meeting requirements. See, *e.g.*, *Public Citizen* v. *United States Dep't of Justice*, 491 U.S. 440 (1989). The standing of a plaintiff to assert such a claim is based on the concrete and immediate injury he or she sustains in seeking and being denied access to the committee's meetings and records. *Id.* at 449. Petitioners, however, do not claim that they were denied access to the Panel's meetings, which were conducted in public after ample notice in the Federal Register. See p. 3, *supra*. Instead, they claim that the Panel's membership was not fairly balanced. But by itself, the composition of an advisory committee's membership does not cause injury. An advisory committee's task is to provide advice, not to take

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in violation of FACA). Indeed, at the time of FACA's enactment, Congress rejected a number of proposals that would have precluded agencies from relying on or using the product of committees convened in violation of the Act. See, *e.g.*, S. 2064, 92d Cong., 1st Sess. § 14, (1971) (permitting injunction against agency actions relying on the product of improperly constituted advisory committee); S. 1637, 92d Cong., 1st Sess. § 11 (1971) (same). But see *Alabama-Tombigbee Rivers Coalition* v. *Department of the Interior*, 26 F.3d 1103, 1106-1107 (11th Cir. 1994) (enjoining agency from "publishing, employing and relying upon" advisory committee report prepared in violation of FACA); cf. *Animal Legal Defense Fund* v. *Shalala*, 53 F.3d 363, 366 n.4 (D.C. Cir. 1995) (dictum).

action. And it is only government action that can lead to cognizable injury.

In this case, petitioners assert that they were injured because the Panel's report will lead to federal funding of human embryo research, and because in various ways, such research would adversely affect their legal rights. Pet. 15. But the Panel's report does not itself lead to federal funding of any human embryo research. The allocation of federal funds to any particular research project, and the decision to approve any particular application, is made by the Director of NIH and the Secretary, not by the Panel or by the Advisory Committee to which the Panel presented its report.[5]

Petitioners contend (Pet. 15) that the Panel's report is "potentially influential" to the decision whether to fund human embryo research. But petitioners' interest in "potential influences" on an agency's decision are not enough to give them standing to sue. The harm they face must be "concrete and immediate" and "likely," not "speculative." *Lujan* v. *Defenders of Wildlife*, 504 U.S. 555, 560-561 (1992). At this stage, given the steps that remain in the administrative process before a funding decision could be made, it is impossible to know whether the Panel's report will furnish any basis for a future deci-

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[5] The government has consistently taken the position that the Panel was neither an ethics advisory board nor an advisory committee covered by the FACA. The district court assumed *arguendo* that the Panel was both (Pet. App. 13a), and the court of appeals held that, in light of its finding that petitioners' claims were moot, there was no need to address those issues. Pet. App. 6a n.2.

sion to provide federal funds for human embryo research.[6]

b. The FACA's requirement that the membership of federal advisory committees be "fairly balanced in terms of the points of view represented and the functions to be performed," FACA § 5(b)(2), is in any event nonjusticiable. Given the practical need for some size limits in order to maintain the efficient operation of collegial bodies, it would be impossible to accommodate every possible point of view regarding the funding of human embryo research. The FACA provides no basis for determining which among the various points of view on the issues to be considered

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[6] Quite aside from the standing obstacles discussed in the text, which are common to all three petitioners, there are additional questions concerning the capacity of each petitioner to bring this action. Petitioners apparently have abandoned their claim that The Michael Fund and Michael Policastro have standing to challenge the Panel's composition under the FACA. As the district court found, there is "no basis" on which to conclude that a decision to fund human embryo research "would diminish funding for research projects involving Down's Syndrome or other genetic disorders," or place Michael Policastro's life at risk. Pet. App. 22a. Furthermore, the district court concluded that Mary Doe, whom petitioners assert is a representative of the 20,000 embryos stored in laboratories in the United States (Pet. 7), does not have standing because she is not a "person" within the meaning of Federal Rule of Civil Procedure 17(c) for whom a guardian *ad litem* can be appointed. Pet. App. 16a-18a; see *Roe* v. *Casey*, 464 F. Supp. 483, 486-487 (E.D. Pa. 1978), aff'd, 623 F.2d 829 (3d Cir. 1980) (in challenge to restrictions on state-funded abortions, district court denies motion to appoint guardians *ad litem* for unborn children, holding that fetuses and embryos "are not persons with a legally protectable interest within the meaning of Fed. R. Civ. P. 17(c) or 24(a)(2) and, thus, the appointment of guardians *ad litem* is neither warranted nor required").

by a federal advisory committee must be represented in order to achieve a fair balance. See *Public Citizen* v. *National Advisory Comm. on Microbiological Criteria for Foods*, 886 F.2d 419, 426 (D.C. Cir. 1989) (Silberman, J., concurring). Nor does the FACA give any guidance about how much representation on a committee is sufficient. For example, the Act does not say whether a member of a committee must actually espouse or advocate a particular view in order to "represent" that view, or whether it is sufficient that the member is acquainted with the view. Nor does the FACA specify whether there must be at least one representative of a point of view, or more than one—and if so, how many more. As to those and other issues that might be imagined, the Act gives no answer at all. See generally *id.* at 426-427 (Silberman, J., concurring).

Given the lack of statutory guidance, the task of filling in the blanks left by Congress's failure to define fair balance—to decide which among the many possible viewpoints should be represented on a committee and to what extent they should be represented—would require a court to engage in "political and ideological determinations." *Public Citizen* v. *Department of Health and Human Servs.*, 795 F. Supp. 1212, 1221 (D.D.C. 1992); accord *Microbiological*, 886 F.2d at 426 (Silberman, J., concurring) (concluding that "the judgment as to what constitutes an appropriate or 'fair' balance of * * * views" is "a political one"). Such judgments are for the agency to make; they are not an appropriate matter for adjudication. *Microbiological*, 886 F.2d at 430 (Silberman, J.,

concurring); *Public Citizen* v. *HHS*, 795 F. Supp. at 1222.[7]

CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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[7] Petitioners assert (Pet. 18 & n.10) that "most courts" have held that a fair balance inquiry would not "defy judicial analysis." The cases they cite—the district court's decision in *Microbiological* and the appeals court's decision in *National Anti-Hunger Coalition* v. *Executive Comm. of the President's Private Sector Survey on Cost Control*, 711 F.2d 1071 (D.C. Cir. 1983)—do not bear out their contention. The district court in *Microbiological* was careful to express its concerns that examination of the committee's membership would lead to "subjective determinations" regarding the committee's composition. 708 F. Supp. 359, 364 (D.D.C. 1988). Indeed, it was on appeal in that case that Judge Silberman concluded that FACA balance claims are nonjusticiable. See 886 F.2d at 430. As for the court of appeals in *National Anti-Hunger Coalition*, it affirmed a district court decision that had concluded that the membership of the Executive Committee of the President's Cost Survey was fairly balanced only after emphasizing that the FACA "[n]owhere * * * explain[s]" what is meant by fair balance, and observing that a requirement to represent every point of view regarding federal fiscal management would be "unworkab[le]." 557 F. Supp. 524, 528 (D.D.C. 1983).